

Appl. No. 10/089,534
Amdt. dated October 26, 2005
Reply to Office Action of July 26, 2005

Docket No. 58009-010600

REMARKS

Claims 13, 21, and 23 have been amended.

New Claim 27 is well supported in the specification and presents no new matter.

Reconsideration of the rejections and objections set forth in the Office Action dated July 26, 2005 is respectfully requested.

Claim Rejections - 35 U.S.C. § 112, ¶ 1

The Examiner has rejected Claims 16-21, 23, and 24 as failing to comply with the written description requirement. Applicants point out support for the previously presented claims as follows:

Claims 16 and 17 are at least supported in page 19, line 15 and page 20, line 10 where cells from one or more individuals are used.

Claim 18 is at least supported in page 20, line 1 where consumption of glucose by the human tissue cells is recorded, and the human tissue cells secrete lactic acid.

Claim 19 is at least supported in page 18, lines 27-30, and page 21, lines 14-18, where the use of human fibroblasts is described in conjunction with allowing the fibroblasts to secrete extracellular matrix components and precursors to collagen fibers.

Claim 20 is at least supported in page 22, lines 10-25, where the use of human keratinocytes to form epithelium is described.

Claim 21 is at least supported in page 24, lines 12-14, where it is disclosed that the simultaneous presence on the fibroin bio-membrane of pre-irradiated human fibroblasts is capable of significantly stimulating the proliferative activity of the human keratinocytes and thereby preventing the onset of the diffpoptosis phenomenon.

Claims 23 and 24 are at least supported in page 17, line 24-25 and lines 29-30 where use of polymers of natural and synthetic origin is disclosed.

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Claim Rejections - 35 U.S.C. § 112, ¶ 2

The Examiner has rejected claims 13, 14, 16-25 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner states that in Claim 13, it appears "using" should be replaced with "including." Claim 13 has been amended to replace "using" with "including."

The term "bio-membrane" has been rejected as uncertain in meaning a scope. The Examiner asks: "How does bio define the membrane?" Applicants submit that bio is a defined prefix that is combined with other words to denote life. Furthermore, Applicants are unsure as to what the Examiner means by "structure that is a membrane and not a membrane is unclear since no structure that defines a membrane is required." A membrane is a well defined term in the art that has been given definitions such as, for example, a thin sheet or layer.

The Examiner states that in Claim 4, the meaning and scope of "specialized tissue cells" is uncertain. The Examiner continues: "[w]hether a cell is 'specialized' is not relative or subjective. On the contrary, a person of ordinary skill in the art of molecular biology would understand what a "specialized cell" is. Indeed, the term specialized cell is well-known in the art.

Finally, Claim 23 has been amended to delete the term "includes" from the language of the claim.

New Claim

Claim 27 is at least supported in page 35, lines 16-29, where the preparation of the fibroin membrane is described.

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Claim Rejections - 35 U.S.C. § 103

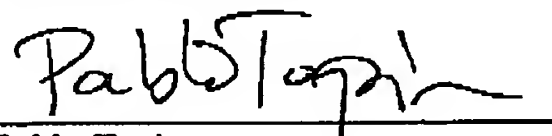
The Examiner has rejected Claims 13, 14, 16-25 under 35 U.S.C. 103(a) as being unpatentable over Santin et al or Gotoh et al. in view of Minoura et al and Naughton et al, and if necessary in view of Bell. Applicants submit that Claim 13 as amended is not unpatentable over the cited references.

In particular, Santin and Gotoh fail to teach a method of the production of a substrate as recited in amended Claim 13. Neither Santin or Gotoh teach the utilization of a membrane with a 3500 molecular weight cut-off for dialysis. Thus Applicants submit that Claim 13 is not unpatentable in view of Santin or Gotoh, in view of Minoura et al and Naughton et al, and if necessary in view of Bell. As such, the rejections to independent Claim 13 should be withdrawn. Furthermore, Claims 14, 16-25 depend from Claim 13. Accordingly, rejections to Claims 14, 16-25 should also be withdrawn.

Conclusion

Applicants submit that the present application is in condition for allowance, and therefore, respectfully request that a timely Notice of Allowance be issued in this case. The Director is authorized to charge any additional fee(s) or any underpayment of fee(s), or to credit any overpayments to Deposit Account Number 50-2638. Please ensure that Attorney Docket Number 58009-010600 is referred to when charging any payments or credits for this case.

Respectfully submitted,



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